

prevent cell migration into the prosthesis. Such materials may be incorporated in any amount which does not adversely affect transparency of the resultant compositions, or cause loss of biocompatibility, e.g. the material may cease to be non-immunogenic. Preferably, the additional material is added in amounts of 0.01 to 50 percent, more preferably from about 0.9% to about 20% by weight.

The prosthesis material of the present invention may be utilized in man or animals by surgical implantation.

One source of commercially prepared collagen suitable for the practice of the present invention is the Collagen Corporation which markets a highly purified, pepsinized calf-skin soluble collagen under the trademark Vitrogen. Since this material is already purified, the collagen gels of the present invention can be made directly by ultracentrifugation.

The invention will be further illustrated by the following examples. Unless otherwise stated, all temperatures are in °C. and all percents are by weight.

EXAMPLE 1

Five (5) fresh tails were obtained from 250-275 g albino rats. The tendons were removed and immediately placed in a petri dish of Tyrode's solution (a commercially available salt solution). The tendons (2.0 grams) were transferred into a 500 ml erlenmeyer flask containing 500 ml 0.5 M HAc at 20° C. (i.e., 15 ml glacial HAc in 500 ml water). The flask was put on a magnetic stirring device in the cold room (at 4° C.) spinning for 2 days. The cold collagen solution was centrifuged in the clinical centrifuge (top speed 1600×g or about 3000-4000 rpm) to sediment debris (10 min, 20°). The supernate from the clinical centrifuge was then placed in a test tube in an ultracentrifuge (Model L8-70) having a No. 40 rotor, and spun at about 40,000 rpm for about 42 hours at 4° C. A pellet about 1 cm thick formed from about 10 ml of supernate.

A pellet was fixed using a solution of 2% formaldehyde made from paraformaldehyde and 3% glutaraldehyde in 0.1 M Cacodylate buffer (available commercially from Aldrich Corporation). About 5 ml of the fixing solution was placed in the centrifuge tube with the pellet for about 30 min. at 4° C. After that the fixing solution was changed and the pellet placed in 5 ml of fresh fixing solution for about 30 minutes at 20° C. The pellet was washed with Tris (0.15M, pH 7.5) and with Cacodylate buffer. The native soluble collagen material, when ultracentrifuged, appeared to form a fairly large, white pellet at bottom of tube on initial fixation. When the pellet was cut from the tube, however, it became apparent that the pellet was really a large, trans-

parent mass of collagen overlying the visible, white pellet. A 5 mm slice of the pellet was subjected to absorbance measurement, and exhibited less than about four percent absorbance over the range of wavelengths of from about 400 to 900 nm, as shown in FIG. 1. When cut with a razor blade, the pellet was tough, like cutting through a piece of leather.

EXAMPLE 2

An ultracentrifuged pellet of native soluble collagen was formed the same as in Example 1 except prior to the step of ultracentrifuging, the collagen solution was dialyzed against water, forming a clear gel. The gel was then transferred to a test tube for ultracentrifugation. A transparent pellet formed as in Example 1. When fixed, the pellet exhibited optical clarity and rigidity, and was leather-like in consistency.

EXAMPLE 3

Thin slices of the pellets formed in Examples 1 and 2 were examined by electron microscopy. The section of the pellet of Example 1 exhibited no apparent structure. The section of the pellet of Example 2 exhibited thin strand-like structures.

The present invention has been described in detail with reference to the preferred embodiments thereof. However, it is appreciated that those skilled in the art, upon consideration of the specification, may make modifications and improvements within the spirit and scope of the invention.

We claim:

1. A prosthetic cornea replacement comprising collagen wherein the collagen component consists essentially of a native, non-fibrillized, transparent, cross-linked collagen material that has less than 5% absorbance of light at 900 nm for a 5 mm thick cross section.

2. The cornea replacement of claim 1, wherein such replacement contains between 0.5 and 20% collagen protein.

3. The cornea replacement of claim 1, further comprising polyhydroxyethylmethacrylate or vitrosin, in a range of between 0.01 to 50% by weight.

4. A native, non-fibrillized, transparent collagen material formed from a soluble collagen solution by ultracentrifuging to form a pellet and fixing said pellet, said collagen material having less than 5% absorbance of light at 900 nm for a 5 mm thick sample and comprising polyhydroxyethylmethacrylate or vitrosin, in a range of from 0.01 to 50 percent by weight, based on the collagen protein.

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